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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BLIZZARD, CHRISTOPHER JAMES

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,711	Applicant(s) DAVIDSON ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 32-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 38-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/26/06, 9/25/06, 11/08/06, 2/16/07, 6/28/07,</u> | 6) <input type="checkbox"/> Other: _____ |
| <u>8/30/07, 9/10/07, 11/08/07, 7/28/08, 2/24/09, 7/17/09, 8/25/09, 1/26/10</u> | |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I claim 1-31 and 38-54 in the reply filed on 11/13/09 is acknowledged.
2. Claims 32-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/09.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-16, and 20-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones (6,123,071) in view of Thornton (6,571,798).
5. Regarding claim 1, Berthon-Jones discloses a breathing arrangement for use between a patient and a structure to deliver gas to a patient, a CPAP device (column 2, lines 31-32), the breathing arrangement comprising; a patient interface including a mouth covering assembly including a flexible cushion (46) structured to sealingly engage around an exterior of a patient's mouth in use (column 4, lines 41-48), a nose assembly (fig. 2, around #44) sealingly engaging with the nasal passages of a patient (column 6, lines 24-26), and a flexible element (64) connecting the mouth covering assembly and the nose assembly (column 6, lines 44-45; column 7, lines 18-20); one inlet conduit (50)

Art Unit: 3771

to deliver breathable gas into the nose assembly (fig. 3a); and a headgear assembly connected to the mouth covering assembly or nose assembly (column 5, lines 4-8), which is inherently removable. Berthon-Jones does not teach the nose assembly being a nozzle assembly including a pair of nozzles structured to sealingly engage within nasal passages of a patient's nose. Thornton teaches a breathing arrangement with a mouth covering (8) as well as a nozzle assembly including a pair of nozzles (fig. 3) structured to sealingly engage within nasal passages of a patient's nose. It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the nose assembly of Berthon-Jones with nozzles as taught by Thornton in order to provide the advantage of less skin contact and irritation around the nose.

6. Regarding claim 2, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches a first chamber (54) formed by the mouth covering a second chamber (52) formed by the nose assembly, analogous to the nozzle assembly of Thornton.

7. Regarding claim 3, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the flexible element (64) being a conduit that allows gas to pass between the first and second chamber (fig. 4b) (column 7, lines 8-10).

8. Regarding claim 4, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Thornton teaches the nozzle assembly connected to an air inlet conduit (54) (column 8, lines 10-14).

Art Unit: 3771

9. Regarding claim 5, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the mouth covering adapted to connected to an inlet conduit (50) to deliver breathable gas to the patients mouth (fig. 4b).

10. Regarding claim 6, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the mouth chamber (54) and the nose chamber (52) being fluidly connected by a duct and this forming a single chamber (fig. 4b).

11. Regarding claim 7, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the structure to be integrally formed as a one piece structure (column 6, lines 35-39).

12. Regarding claim 8, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the cushion (46) having a face contacting portion (fig. 4a, around #46) and a non face contacting portion (fig. 4a, around #56) removably attached to a rigid frame (42).

13. Regarding claim 9, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the sides of the cushion partially collapsing (column 4, lines 62-67), and thus considered to be a gusset portion.

14. Regarding claim 10, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the cushion having a side wall (fig. 4b), a rim extending from the side wall (fig. 4b), and a membrane surrounding the rim (fig. 4b).

Art Unit: 3771

15. Regarding claim 11, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the mouth cushion and the nasal cushion, analogous to the nozzle assembly, being able to be a single integral element (column 6, lines 35-38). Therefore, it would have been obvious to have the nozzles as taught by Thornton to extend from the side wall of the cushion as taught by Berthon-Jones in order to provide the advantage of a less bulky device.

16. Regarding claim 12, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Thornton teaches adjust of the nozzles allowing them to be angled (column 8, lines 22-24).

17. Regarding claim 13, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the inner edge of the membrane forming an aperture have a general oval shape (fig. 2, around #56 and #54).

18. Regarding claim 14, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the mouth cushion having an arcuate protruding portion along the upper and lower edge, in that it is curved and the ends protrude more than the center (column 4, lines 25-27)(fig. 1c).

19. Regarding claim 15, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the rim being provided on lateral sides of the side walls of the cushion (fig. 2).

20. Regarding claim 16, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the membrane being thinner than the rim (fig. 4b)(column 4, lines 61-67).

Art Unit: 3771

21. Regarding claim 20, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the patient interface having a frame (48) with an inlet conduit (50) coupled at one end of it (fig. 3a) and an anti-asphyxia valve (56) coupled at the opposite side (fig. 3a).

22. Regarding claim 21, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the device wherein the nose assembly, analogous to the nozzle assembly taught by Thornton, is not in fluid communication with the mouth cushion (column 6, lines 13-15).

23. Regarding claim 22, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the body contacting portions to be made of silicone rubber (column 4,61-62), which could be considered to be a gel-like material.

24. Regarding claim 23, the combination of Berthon-Jones and Thornton teach the claimed invention wherein the nozzles are formed separately from the cushion.

25. Regarding claim 24, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the frame having corrugations (30) (fig. 4a) that would add flexibility to the frame.

26. Regarding claims 25, 26 and 28, the combination of Berthon-Jones and Thornton teach the claimed invention wherein it can be seen in figure 3 of Thornton that each nozzle includes a conduit having a concertina configuration (50), that could also be considered to rounded recesses or a gusset portion, that adds flexibility to the conduit

Art Unit: 3771

and would change the sealing force in accordance with the treatment pressure if their length was changed (column 8, lines 19-30).

27. Regarding claim 27, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Thornton teaches the nozzle conduits having varying cross section (fig. 3).

28. Regarding claim 29, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Thornton teaches each nozzle include a nasal pillow (30), analogous to a thin membrane surrounding each nozzle.

29. Regarding claim 30, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Thornton teaches a nozzle support member (50) that engages the nozzles to support the nozzles in a rigid configuration for alignment (column 8, lines 19-30).

30. Regarding claim 31, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the cushion (46) having a boomerang shape (fig. 2).

31. Regarding claim 38-41 and 43-45, the combination of Berthon-Jones and Thornton teach the claimed invention above, further wherein Berthon-Jones teaches the membrane had a substantially flat profile (fig. 2).

32. Regarding claim 42, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches side wall of the cushion (46), that would have the nozzles as taught by Thornton attached as disclosed in claim 11 above,

Art Unit: 3771

being curved away from the frame (fig. 4b), and therefore including an arcuate protruding portion.

33. Regarding claims 46-54, the combination of Berthon-Jones and Thornton teach the claimed invention wherein Berthon-Jones teaches the side wall of the cushion (46) being mounted in a removable manner to the frame (fig. 4b).

34. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones (6,123,071) and Thornton (6,571,798) as applied to claim 1 above, and further in view of Trimble (4,782,832).

35. Regarding claims 17-19, the combination of Berthon-Jones and Thornton teach the claimed invention except for the specific structure of the headgear assembly.

Trimble teaches a breathing arrangement with a headgear assembly (24) (fig. 1) wherein it has a strap that is routed around the top of a patient's ears (fig. 1), could be rotated around the patient's head in use for adjustment as it does not have any straps prohibiting this movement (fig. 1) and is connected to the patient interface using clips and Velcro (column 6, lines 60-68, column 7, lines 1-2), analogous to a snap fit. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Berthon-Jones and Thornton with headgear as taught by Trimble in order to provide the added advantage of a secure fit of the patient interface.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is

Art Unit: 3771

(571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771